4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3787]

Electromagnetic Compatibility of Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Electromagnetic Compatibility (EMC) of Medical Devices." FDA has developed this guidance document to recommend information that should be provided in a premarket submission (i.e., premarket approval application (PMA), humanitarian device exemption (HDE), premarket notification (510(k)) submission, investigational device exemption (IDE), De Novo request, and certain biologics license applications (BLAs) and investigational new drug (IND) applications to demonstrate electromagnetic compatibility (EMC) for electrically powered medical devices and medical devices with electrical or electronic functions. This guidance provides specific technical information to address the recommendations originally described in the guidance entitled "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices," which was published July 11, 2016 (2016 EMC guidance).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-3787 for "Electromagnetic Compatibility (EMC) of Medical Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Electromagnetic Compatibility (EMC) of Medical Devices" to the Office of Policy, Center for

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Seth J. Seidman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1108, Silver Spring, MD 20993-0002, 301-796-2477; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to recommend information that should be provided in a premarket submission (i.e., PMA, HDE, 510(k), IDE, De Novo request, and certain BLAs and IND applications) to demonstrate EMC for electrically powered medical devices and medical devices with electrical or electronic functions. Typically, the review of EMC information in a submission is based on the risk associated with malfunction or degradation of the medical device under consideration, where malfunction or degradation could be caused by inadequate EMC. The review is also based on the use of appropriate consensus standards. This guidance, when final, will replace the FDA guidance entitled "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices" (2016 EMC guidance), which was published July 11, 2016. This guidance provides additional technical information to address the recommendations in the 2016 EMC guidance.

FDA recognizes and anticipates that the Agency and industry may need up to 1 year to perform activities to operationalize the policies within the guidance, *only* for in vitro diagnostic products. Because this guidance generally reflects current practice for the assessment of EMC

for other device types, but some activities to fully operationalize the policies are needed (e.g., updates to eSTAR[1]), FDA intends to implement this guidance 60 days after issuance for device types within the scope of this guidance, excluding in vitro diagnostic products. If new information regarding electromagnetic compatibility as outlined in this guidance is not included in a premarket submission for an in vitro diagnostic received by FDA before or up to 1 year after the publication of this guidance or for other device types within the scope of this guidance before or up to 60 days after the publication of this guidance, FDA does not generally intend to request such information during the review of the submission. FDA does, however, intend to review any such information if submitted.

A notice of availability of the draft guidance appeared in the *Federal Register* of November 17, 2020 (85 FR 73276). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of scope; addressing the use of IEC 60601-1-2:2020, which was published after the draft guidance was issued; and adding a transition period to facilitate the implementation of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on EMC of medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products or from the Center for Biologics Evaluation and

[1] Available at https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program.

Research at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances. This guidance document is also available at https://www.regulations.gov and https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Electromagnetic Compatibility (EMC) of Medical Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400057 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
860, subpart D	De Novo classification process	0910-0844
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting	0910-0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: May 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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